

PATENT COOPERATION TREATY

PCT/JP2003/013743



PCT

 INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
 (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P03-114	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/JP2003/013743	International filing date (day/month/year) 28 October 2003 (28.10.2003)	Priority date (day/month/year) 29 October 2002 (29.10.2002)	
International Patent Classification (IPC) or national classification and IPC A01K 67/027, A61K 45/00, A61P 13/08, G01N 33/15, 33/50			
Applicant TAIHO PHARMACEUTICAL CO., LTD.			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.	
2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.	
3. This report is also accompanied by ANNEXES, comprising:	
a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:	
<input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).	
<input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.	
b. <input type="checkbox"/> (sent to the International Bureau only) a total of _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).	
4. This report contains indications relating to the following items:	
<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input checked="" type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application

Date of submission of the demand 02 February 2004 (02.02.2004)	Date of completion of this report 20 May 2004 (20.05.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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International application No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☐ the description:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- pages _____, as originally filed/furnished
- pages* _____, as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 24

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☒ the claims, or said claims Nos. 24 are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 24

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the
Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with
the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ see Supplemental Box for further details.

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	1-23	YES
	Claims		NO
Inventive step (IS)	Claims	1-23	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-23	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: EP, 1055426, A (Taiho Pharmaceutical Co., Ltd.), 29 November, 2000 (29.11.00)

Document 2: "Basic and Clinical Examination of Prostatitis (in Japanese)," (Toshihiro Goto), Nishinihon Journal of Urology, 1988, Vol. 50, pages 446-455

Document 3: "Sex-hormone-induced Inflammation and Fibromuscular Proliferation in the Rat Lateral Prostate," (C.L. Robinette), Prostate, 1988, Vol. 12 (3), pages 271-286

Document 4: "Development of a Mouse Model for Nonbacterial Prostatitis," (D.W. Keetch, et al.), J. Urol., July 1994, Vol. 152 (1), pages 247-250

Document 5: "Rat Model of Experimentally Induced Abacterial Prostatitis," (M.D. Lang, et al.), Prostate, 1 November, 2000 (01.11.00), Vol. 45 (3), pages 201-206

The subject matters of claims 1-23 appear to be novel and to involve an inventive step in view of documents 1-5 cited in the ISR.

None of the documents describes or suggests that if hydrochloric acid is injected under the prostate membrane of a nonhuman animal, an abacterial prostatitis model animal having the tissue disorders and lower urinary tract disorders characteristically observed in human chronic abacterial prostatitis can be obtained.